

## Cardiva gets FDA nod for extravascular closure device

07 February 2013 | News | By BioSpectrum Bureau



**Singapore:** Cardiva Medical has received pre-market approval for the Vascade vascular closure system from the US Food and Drug Administration. Vascade, an extravascular closure device, utilizes a unique delivery system based on a proprietary collapsible disc technology that provides temporary hemostasis during the procedure which eliminates the need for an intra-vascular component. Secure and rapid hemostasis is achieved with Vascade by the deployment of a thrombogenic resorbable collagen patch at the arteriotomy of the femoral artery.

Clinical data from a prospective, multi-center, randomized 420 patient trial demonstrated that the Vascade VCS is clinically and statistically superior in both safety and efficacy compared to manual compression, the gold standard for vascular closure for patients undergoing percutaneous procedures through the femoral artery. The trials were held in the US and Australia.

"We are thrilled to receive PMA approval for Vascade," said Mr Charles Maroney, president and CEO. "We appreciate the effort of our clinical investigators who worked with us to achieve this important milestone and establish a new 3rd generation closure technology. Cardiva is well positioned to bring this technology to the marketplace to increase patient throughput and

provide a safer and more effective alternative to manual compression across the US."

Dr James Hermiller of The Heart Center, Indianapolis, US, who served as principal investigator for the trial said, "I am extremely pleased with the outstanding clinical performance of Vascade and with the extraordinary contributions by over 65 clinical investigators and their staff at over 20 clinical sites in the US and Australia who facilitated the study. With PMA approval, Vascade will now be available in the US to all physicians who need safe and effective vascular closure."

Dr Frank Zidar, clinical investigator at The Heart Hospital of Austin, US, commented, "Vascade is a new generation of extravascular closure technology that offers significant advantages over conventional closure devices and manual compression. I am excited to be able to provide Vascade to my patients and to integrate it into my practice."